

FDA NEWS RELEASE

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FDA proposes new food safety standards for foodborne illness prevention and produce safety

Public encouraged to comment on new proposals

The U.S. Food and Drug Administration today proposed two new food safety rules that will help prevent foodborne illness. The proposed rules implement the landmark, bipartisan FDA Food Safety Modernization Act (FSMA) and are available for public comment for the next 120 days. The FDA encourages Americans to review and comment on these important proposed rules.

The proposed rules build on significant strides made during the Obama Administration, including the first egg safety rule protecting consumers from *Salmonella* and stepped up testing for *E. coli* in beef as well as existing voluntary industry guidelines for food safety, which many producers, growers and others currently follow.

The rules follow extensive outreach by the FDA to the produce industry, the consumer community, other government agencies and the international community. Since January 2011, FDA staff have toured farms and facilities nationwide and participated in hundreds of meetings and presentations with global regulatory partners, industry stakeholders, consumer groups, farmers, state and local officials, and the research community.

“The FDA Food Safety Modernization Act is a common sense law that shifts the food safety focus from reactive to preventive,” said Health and Human Services Secretary Kathleen Sebelius. “With the support of industry, consumer groups, and the bipartisan leadership in Congress, we are establishing a science-based, flexible system to better prevent foodborne illness and protect American families.”

The burden of foodborne illness in the United States is substantial. One in six Americans suffer from a foodborne illness every year. Of those, nearly 130,000 are hospitalized and 3,000 die from their illness. Preventing foodborne illnesses will improve public health, reduce medical costs, and avoid the costly disruptions of the food system caused by illness outbreaks and large-scale recalls.

These two FSMA rules are part of an integrated reform effort that focuses on prevention and addresses the safety of foods produced domestically and imported, with additional rules to be published shortly.

The first rule proposed today would require makers of food to be sold in the United States, whether produced at a foreign- or domestic-based facility, to develop a formal plan for preventing their food products from causing foodborne illness. The rule would also require them

to have plans for correcting any problems that arise. The FDA seeks public comment on this proposal. The FDA is proposing that many food manufacturers be in compliance with the new preventive controls rules one year after the final rules are published in the Federal Register but small and very small businesses would be given additional time.

The FDA also seeks public comment on the second proposed rule released today, which proposes enforceable safety standards for the production and harvesting of produce on farms. This rule proposes science- and risk-based standards for the safe production and harvesting of fruits and vegetables.

The FDA is proposing that larger farms be in compliance with most of the produce safety requirements 26 months after the final rule is published in the Federal Register. Small and very small farms would have additional time to comply, and all farms would have additional time to comply with certain requirements related to water quality.

“The FDA knows that food safety, from farm to fork, requires partnership with industry, consumers, local, state and tribal governments, and our international trading partners,” said FDA Commissioner Margaret A. Hamburg, M.D. “Our proposed rules reflect the input we have received from these stakeholders and we look forward to working with the public as they review the proposed rules.”

Before issuing the two rules, the FDA conducted extensive outreach that included five federal public meetings and regional, state, and local meetings in 14 states across the country as well as making hundreds of presentations to ensure that the rules would be flexible enough to cover the diverse industries to be affected. The FDA also visited farms and facilities of varying sizes.

“We know one-size-fits-all rules won’t work,” said Michael R. Taylor, the FDA’s deputy commissioner for foods and veterinary medicine. “We’ve worked to develop proposed regulations that can be both effective and practical across today’s diverse food system.”

Additional rules to follow soon include new responsibilities for importers to verify that food products grown or processed overseas are as safe as domestically produced food and accreditation standards to strengthen the quality of third party food safety audits overseas. Improving oversight of imported food is an important goal of FSMA. Approximately 15 percent of the food consumed in the United States is imported, with much higher proportions in certain higher risk categories, such as produce. The FDA will also propose a preventive controls rule for animal food facilities, similar to the preventive controls rule proposed today for human food.

The FDA plans to coordinate the comment periods on the major FSMA proposals as fully as possible to better enable public comment on how the rules can best work together to create an integrated, effective and efficient food safety system.

For more information:

- [Federal Register Notice for the Proposed Rule “Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food”](#)²
- [Federal Register Notice for the Proposed Rule “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption”](#)³
- [FDA Food Safety Modernization Act \(FSMA\)](#)⁴

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